

Notice of Allowability

Application No.

10/776,021

Applicant(s)

SHEHADA, RAMEZ EMILE
NECOLA

Examiner

MELANIE J. HAND

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 1/15/08.
2. ☒ The allowed claim(s) is/are 1,4-6,8-15 and 103-105.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>200804171</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Melanie J Hand/
Examiner, Art Unit 3761

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Please amend claim 1 to read as follows:

**Claim 1. An implantable surgical drain configured to be placed against at least one tissue within a patient's body for draining fluid and sensing at least one physiological property of the tissue, comprising: a) an elongated conduit housing configured to be implanted in the patient's body and to rest against a substantial length of a first tissue within the body, and to drain wound fluid from the body, the elongated conduit comprising: i. a first and a second surface on an outer side and along the length of the elongated conduit; ii. a plurality of drain openings in the first and the second surface positioned along substantially the entire length of the elongated conduit, configured to drain wound fluid from the body; iii. a first and a second drain lumen positioned within the elongated conduit housing in fluid communication with the plurality of the drain openings; iv. at least one sensing element positioned along the first surface in proximity to the drain openings of the elongated conduit configured to sense a physiological property of the first tissue; and v. an at least one inflatable compartment positioned within the elongated conduit housing between the first and the second drain lumens, positioned behind the at least one sensing element, configured when inflated to push the at least one sensing element in a substantially orthogonal direction with respect to the first surface against the first tissue so as to enhance contact between the sensing element and the first tissue; and b) a tube in fluid communication with the first and the second drain lumens configured to transport the drained wound fluid out of the body. ---
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Authorization for this examiner's amendment was given in a telephone interview with Marc Brown on April 17, 2008.

REASONS FOR ALLOWANCE

Allowable Claims

2. Claims 1, 4-6, 8-15 and 103-105 are allowed.

3. The following is an examiner's statement of reasons for allowance: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests an implantable surgical drain having at least one inflatable compartment positioned within an elongated conduit housing and between first and second drain lumens positioned therein, the inflatable compartment being positioned behind the at least one sensing element and when inflated, is configured to push the at least one sensing element in a substantially orthogonal direction with respect to a first surface of the conduit, against the first tissue so as to enhance contact between the sensing element and the first tissue.

The closest prior art of record is U.S. Patent No. 7,291,110 to Sahatjian. Sahatjian teaches an implantable catheter within a stent configured to be placed against at least one tissue in the form of a vessel wall having a lesion and configured to sense at least one physiological property of the tissue, specifically the biochemical composition of the lesion by acoustic signal. Sahatjian teaches an elongated conduit housing in the form of the stent having a first and second surface on an outer side of and along a length of the elongated conduit. The stent has openings however, the stent is not configured for draining wound fluid as recited in claim 1 and thus the openings present thereon are not a plurality of drain openings configured to drain wound fluid from the body. Sahatjian teaches at least one sensing element in the form of an array 52 of piezoelectric sensing elements in proximity to the openings on the stent. However

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these elements are along a surface of the catheter, not the conduit/stent as required in claim 1. Sahatjian teaches at least one inflatable compartment in the form of an inflatable balloon 50 in tube form that is positioned within the elongated conduit housing, i.e. the stent. The inflatable compartment 50 has the array of elements 54 thereon and is thus positioned behind the at least one sensing element 54 and is configured, when inflated, to push the at least one sensing element in a substantially orthogonal direction to the first surface of the stent against the first tissue (vessel wall having the lesion) so as to enhance contact between the sensing element 54 and the first tissue. Sahatjian does not teach that the stent or the openings thereon are configured for draining wound fluid from the body, as they are not configured for any type of draining. Sahatjian does not teach any drain lumens within the elongated conduit housing (stent) nor does Sahatjian teach a tube in fluid communication with first and second drain lumens configured to transport the drained wound fluid from the body. Further it would not be obvious to one of ordinary skill in the art to modify the device of Sahatjian so as to be configured for draining, as the device of Sahatjian is a catheter intended for diagnostic testing of the instant lesion, and flow of fluid, such as blood through the vessel wall, would disturb or interfere with the acoustic signals sent and received by sensing elements 84, and the action of draining would potentially loosen or rupture the lesion, potentially causing a stroke or other blockage. Sahatjian also then does not fairly suggest modifying the instant device so as to have a tube in fluid communication with the instant stent configured to transport drained wound fluid out of the body, as this action could also potentially cause rupture of the lesion and increase the risk of stroke or other cardiac events.

It is noted herein that there exist several other publications sharing a common inventor and claiming similar subject matter. These publications are U.S. Patent Nos. 7,267,671, 7,264,616, 7,241,287 and 7,244,251. However, the earliest priority date claimed by each is

February 7, 2003, which is the filing date of this application, and none of these patents teaches or suggest an inflatable compartment in any form.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

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/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763